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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,372	01/09/2004	Donald J. Larnard	22521-19CON	7747
31292	7590	11/15/2004	EXAMINER	
CHRISTOPHER & WEISBERG, P.A. 200 EAST LAS OLAS BOULEVARD SUITE 2040 FORT LAUDERDALE, FL 33301			STOKES, CANDICE CAPRI	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/754,372	LARNARD, DONALD J.	
	Examiner	Art Unit	
	Candice C. Stokes	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-36 is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/09/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 16-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore et al (US 2003/0144593). Whitmore et al disclose a surgical device 20 for thermally affecting soft tissue comprising a structure 22 for enveloping and receiving at least a portion of a surgical instrument, wherein the structure is configured to control thermal energy transfer between the structure 22 and the soft tissue. As to Claim 2, device 20 also comprises a supply 26 of thermo-conductive fluid in fluid communication with the structure 22. In anticipation of Claim 3, Whitmore et al disclose an alternate embodiment that includes a thermoelectric module 775 "through which a low voltage current may be introduced to create an increased temperature adjacent a patient's anatomy" [0058]. The module is in thermal communication with the structure 22 as best shown in FIG. 7. With respect to Claim 4, device 20 further comprises a bundle of thermo-conductive fiber 24 in thermal communication with the structure 22. As to Claim 5, "a heat exchanger to warm or cool the circulating fluid may be included. Thus, a predetermined temperature of the liquid that circulates through the expanded structure or sheath 22 may be used to warm or cool adjacent tissues" [0045]. Whitmore et al also disclose a surgical device 20 wherein the structure comprises a sheath 22 to envelope an end of the surgical instrument, wherein the sheath includes an open proximal end and a closed distal end defining an

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interior surface and an exterior surface. The device 20 also includes a fluid conduit 26 containing a fluid inlet 426 and fluid outlet 427 as best shown in FIG. 4. Furthermore, with respect to Claims 6,8 and 19, the fluid conduit is affixed to the exterior surface of the sheath 22. As to Claim 7, Whitmore et al disclose the structure 22 is an expandable sheath. Therefore, it is inherent that the sheath is made form a resilient elastic material. Regarding Claim 9, Fig. 4 shows the fluid conduit is affixed to the interior surface of the sheath. As to Claim 10-12, FIG. 4 shows that the thermal transfer region can be formed longitudinally and horizontally and the fluid conduit is integrated with the sheath. With respect to Claim 13, FIG. 7 shows that the arrows show that the thermal transfer region is and spiral. As to Claims 16 and 17, Whitmore's device for thermally affecting tissue further comprises a fluid conduit 22 including an inlet and an outlet. "A first passage is associated with the first substantially enclosed volume for directing a warm fluid therein". Furthermore, "the first substantially enclosed volume includes a second passage for removing fluid therefrom. The means for attaching the fluid conduit to a tissue-contacting surface of a medical instrument is sheath 22. Finally, as to Claim 19, Fig. 7 shows the fluid conduit affixed to the exterior surface of the structure. Whitmore et al discloses all the features of the claimed invention except for structure and fluid conduit being a substantially planar thermal transfer region. However, Whitmore et al teaches "the periphery of the outer sheath 522 and inner sheath 524 may be any shape including non-circular shapes" ([0060]). It would have been an obvious matter of design choice to make the periphery or thermal transfer region substantially planar, since such a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art.

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Allowable Subject Matter

Claims 14-15, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Claims 33-36 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (571) 272-4714. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-4714.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Candice C. Stokes


PEDRO PHILOGENE
PRIMARY EXAMINER